P. :NT COOPERATION TREA.

From the INTERNATIONAL BUREAU

# PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

| | |
|---|---|
| **Date of mailing** (day/month/year)<br>31 May 2001 (31.05.01) | |
| **International application No.**<br>PCT/AU00/01159 | **Applicant's or agent's file reference**<br>Schu6 |
| **International filing date** (day/month/year)<br>25 September 2000 (25.09.00) | **Priority date** (day/month/year)<br>24 September 1999 (24.09.99) |
| **Applicant**<br>RUDOV, David | |

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

23 April 2001 (23.04.01)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

| | |
|---|---|
| **The International Bureau of WIPO**<br>**34, chemin des Colombettes**<br>**1211 Geneva 20, Switzerland** | Authorized officer<br>J. Leitao |
| Facsimile No.: (41-22) 740.14.35 | Telephone No.: (41-22) 338.83.38 |

Form PCT/IB/331 (July 1992)

4061823

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159

**A. CLASSIFICATION OF SUBJECT MATTER**

Int Cl[7]: A61K 35/78, A61P1/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61K 35/78, A61P 1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: Cereal, Rye, Ryegrass, Secale Cereals, Barley, Wheat, Triticum, T Durum, T Compactum, Triticale, Corn, Rice, Oats, Maize, Sorghum, Millet, Extract, Side effects, Indigestion, Gas Production, Eructation, Constipation, Diarrhoea, Rash, Headache, Nausea, Dizziness

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 91/11191 A (RUDOV DAVID) 8 August 1991<br>Whole document | 7,9-12<br>23,25-28 |
| X | US 3787591 A (YOSHIHIDE HAGIWARA) 22 January 1974<br>Whole document | 7,9-12,23,<br>25-28 |
| X | AU 81985/87 A (RUDOV DAVID) 9 June 1988<br>Whole document | 1,3-7,9-13,<br>15-23,25-29,31-38 |

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 2 November 2000 | 14 NOV 2000 |
| **Name and mailing address of the ISA/AU** | **Authorized officer** |
| AUSTRALIAN PATENT OFFICE<br>PO BOX 200<br>WODEN ACT 2606 AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No.: (02) 6285 3929 | SHUBHRA CHANDRA<br>Telephone No.: (02) 6283 2264 |

Form PCT/ISA/210 (second sheet) (July 1998) COPSAO

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | Patent Abstract of Japan, JP 2000044459 (TEKUNOOBURU: KK) 15 February 2000 | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | EP 0620007 A (SOKEN CO.LTD) 19 October 1994 Whole document | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | CN 1098851 (TAIPINGYANG SCIENCE AND TECH I (CN) 22 February 1995 | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | CN 1106227 (ZHENXING ROODSTUFF FACTORY SHE (CN) 9 August 1995 | 1,3-7,9-13,15-23,25-29,31-38 |
| X | WO 95/06459 A (HELSINKI UNIVERSITY LICENSING LTD) 9 March 1995 Whole document | 1,3-7,9-13, 15-23,25-29,31-38 |
| A | HIDVEGI ET AL, CANCER BIOTHERAPY AND RADIO PHARMACEUTICALS (1999) 14, No.4, 277-289 | 1-38 |
| X | BHATTACHARYA ET AL, SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY (1998) 33, 159-163 | 1,3-7,9-13,15-23, 25,29,31-38 |

# INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 00/01159

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| WO | 91/11191 | AU | 72175/91 | | | | |
| US | 3787591 | NONE | | | | | |
| AU | 81985/87 | CA | 1298558 | DK | 6335/87 | EP | 279984 |
| | | HK | 1184/94 | NZ | 222758 | SG | 1087/94 |
| | | US | 4943433 | WO | 88/04176 | | |
| JP | 00044459 | NONE | | | | | |
| EP | 620007 | CA | 2115707 | JP | 6298658 | US | 5728384 |
| CN | 1098851 | NONE | | | | | |
| CN | 1106227 | NONE | | | | | |
| WO | 95/06459 | AU | 75384/94 | EP | 717613 | FI | 933833 |

END OF ANNEX

PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



14

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
|---|---|---|
| Schu6 | | |
| International Application No. | International Filing Date *(day/month/year)* | Priority Date *(day/month/year)* |
| PCT/AU00/01159 | 25 September 2000 | 24 September 1999 |

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A61K 35/78, A61P 1/00

Applicant

RUDOV, David

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

[X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheet(s).

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| I | [X] | Basis of the report |
| II | [ ] | Priority |
| III | [ ] | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | [ ] | Lack of unity of invention |
| V | [X] | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | [ ] | Certain documents cited |
| VII | [ ] | Certain defects in the international application |
| VIII | [ ] | Certain observations on the international application |

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 23 April 2001 | 1 November 2001 13 NOV 2001 |

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE
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Authorized Officer

SHUBHRA CHANDRA
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INTERNATIONAL PRELIM[illegible]Y EXAMINATION REPORT

[illegible]national application No.
PCT/AU00/01159

## I. Basis of the report

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1-10,** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **11-17,** received on **31August 2001** with the letter of **31August 2001**
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] Contained in the international application in written form.
- [ ] Filed together with the international application in computer readable form.
- [ ] Furnished subsequently to this Authority in written form.
- [ ] Furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|---|---|---|
| Novelty (N) | Claims 1-37 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-37 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-37 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

D1 AU 81985/87

D2 Patent abstract of Japan, JP 2000044459

D3 EP 0620007

D4 CN 1098851

D5 CN 1106227

D6 WO 95/06459

D7 BHATTACHARYA ET AL SCANDINAVIAN JOURNAL OF GASTROENTROLOGY (1998) 33, 159-163.

D8 WO 91/11191

D9 US 3787591

None of the above mentioned citations disclose or suggest the invention as defined in the amended claims. Therefore, Claims 1-37 are novel and inventive.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 April 2001 (05.04.2001)

PCT

(10) International Publication Number
WO 01/22980 A1

(51) International Patent Classification[7]: A61K 35/78, A61P 1/00

(21) International Application Number: PCT/AU00/01159

(22) International Filing Date:
25 September 2000 (25.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| PQ 3050 | 24 September 1999 (24.09.1999) | AU |
| PQ 4064 | 16 November 1999 (16.11.1999) | AU |

(71) Applicant and
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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *With international search report.*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 01/22980 A1

(54) Title: SIDE EFFECTS TREATMENT

(57) Abstract: The invention provides a novel use of a substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. The use is for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal. The invention also provides a product for the adjunct treatment of animals, a process for the adjunct treatment of animals, an adjunct secondary treatment product effective to reduce the incidence or severity of side effects, and a process for enhancing the therapeutic treatment of an animal.

# SIDE EFFECTS TREATMENT

This invention relates to processes and products for the treatment of animals, including humans, to reduce side effects associated with other chemical treatment regimes.

The treatment of animals including veterinary treatment of domestic animals, sporting animals such as race horses, and livestock by use of chemical substances (including systemic and local treatments by ingestion, intravenous, and subcutaneous application as well as by external or topical application) frequently leads to undesirable side effects of the treatment regime. There is a very wide range of such side effects such as effects caused by systemic circulation of the treatment substances or caused by by-products or caused by reaction products. Such side effects include for example rashes, headaches, nausea, dizziness, vision difficulties, circulatory problems and disorders, as well as general or local sensations of pain. Other side effects include gastrointestinal problems, e.g. reflux, indigestion, gas production and eructation, constipation, diarrhoea. The side effects can be due to toxic or allergic reactions by the subject as well as being effects of the mechanisms of the substances. For example, the use of antibiotics is frequently associated with digestive problems when taken by ingestion due to the action of the antibiotics in inhibiting or killing normally present and beneficial micro-organisms in the digestive tract.

Antibiotics are frequently prescribed and used in the treatment of animals, including humans, for micro-organism infections, particularly bacterial infections and undesired side effects of the antibiotics of the general kind outlined above are observed. Such side effects frequently require separate treatment, such as treatment with antihistamines to manage mild allergic responses.

The condition known as "chronic fatigue syndrome" or "CFS" is believed to be caused or associated with bacterial infection and is therefore known to be treated with

antibiotics. Undesired side effects are therefore associated with treatment of CFS patients with antibiotics.

The administration of antibiotics to animals, including human patients, both before, during and after surgery or other interventions including intrusive examinations is common. Such administration of antibiotics is carried out to avoid or reduce trauma that may be commonly associated with the procedures. For example, respiratory infections, including bacterial and viral infections, are commonly encountered in post operative patients because patients are more susceptible at such times due to the immune system being compromised or more vulnerable following the traumatic procedures and due also to the condition for which the procedure has been carried out. The administration of antibiotics in such circumstances is a frequently used as a precautionary measure. The antibiotics are frequently administered intravenously together with other substances such as saline solutions, analgesics, sedatives. The administration of antibiotics or other chemical treatments as precautionary or preventative treatments before, during or after traumatic events or during immuno compromised or vulnerable conditions can be associated with the undesired side effects of the kind discussed above.

It is an object of the present invention to provide methods and products for reducing the incidence or severity of undesired side effects associated with chemical treatments of animals, including humans.

According to the present invention there is provided a method of treating an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary

treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals. the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal. the method of treating further comprising administering to the animal. in conjunction with the administration of the primary treatment substance. a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

The treatment of an animal. including a human. with a primary treatment substance having undesirable side effects with the secondary substance as an adjunct to the primary treatment is based on the unexpected and surprising reduction of the incidence or severity of the side effects resulting apparently from the adjunct treatment. For example. it has been observed that in the treatment of CFS using antibiotics. the normally or occasionally expected and observed side effects of the antibiotic treatment regime were significantly reduced in subjects having the adjunct treatment with the secondary substance according to the process of the present invention.

Likewise. it has been observed that the treatment of race horses for injured or pathological conditions involving administration of chemical substances such as antibiotics. has frequently necessitated the horses being rested or "spelled" or "turned out" for several months due to side effects of the primary treatment. However the administration of a secondary substance in accordance with the present invention to the animals as an adjunct to

the primary treatment has surprisingly led to horses following thorough veterinary inspections being declared fit to be raced again after much shorter resting or spelling periods.

Broadly the secondary substance used in the present invention comprises a pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. Such a substance will be referred to in this specification as "a substance of the kind described".

The references throughout this specification to a primary chemical treatment are intended to cover any treatment with a foreign substance or material, whether by external, topical, transdermal, subcutaneous, intravenous application or by ingestion, the foreign substance or material including pharmaceuticals, herbal or naturopathic substances, and organic and inorganic elements or compounds, and carriers or excipients therefor.

According to a first particular aspect of the present invention, there is provided a novel use of the substance of the kind described for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

According to a second particular aspect of the present invention there is provided a product for the adjunct treatment of animals, including humans, the product comprising a substance of the kind described in an effective quantity to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In a third particular aspect of the present invention there is provided a process for the adjunct treatment of animals, including humans, undergoing a primary chemical treatment, the process including the steps of administering an effective quantity of a substance of the

kind described to the animal in a manner and over a period of time to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In accordance with a fourth particular aspect of the present invention there is provided an adjunct secondary treatment product effective to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal, the product comprising a substance of the kind described provided in a concentration and medium for administration to the animal to achieve the side effect reduction.

In a fifth particular aspect of the present invention there is provided a process for enhancing a therapeutic treatment of an animal by reducing the incidence or severity of side effects associated with a primary chemical treatment of the animal, the process comprising administering to the animal a substance of the kind described in a quantity and over a period of time to be effective to achieve the side effect reduction.

Preferably in the processes of the invention the administration of the adjunct secondary treatment substance occurs simultaneously with, and may also be continued after, the primary chemical treatment period.

A substance of the kind described is already known from Australian patent specification No. AU-81985/87 (Patent No. 599725) (equivalent US Pat. No. 4,943,433) by the present applicant. In this prior patent specification, a range of possible uses of the substance are described or indicated in passing. This earlier patent specification and subsequent uses of the commercial product produced according to the prior patent specification have resulted in recognition of range of physiological indications including anti-inflammatory, immunomodulatory, and analgesic activity. However, the activity of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is totally unexpected and surprising leading

to novel new uses of the substance hitherto unknown and with no reason to expect or suspect or seek such new uses.

Reference may be made to AU-81985/87 for further background and description of a substance of the kind described useable in the present invention in its various aspects. References herein to "cereal plants" is to be interpreted to include wild grasses. However, a particular cereal plant found to be particularly useful as a source of the extract is *Secale Cereale* or "rye grass".

Extracts from barley and wheat are also believed to be effective. The wheat may comprise Triticum vulgare or aestivum, T. durum, T. compactum, or triticale. Corn, rice, oats, maize, sorghum and millet may also be effective.

Preferably the extract is derived from the green leafy part of the plant, or at least principally from this part of the plant, although additional green parts such as stalk may be included. The leaves of the plant are preferably treated to yield the extract before the plant reaches flowering or seed production stage of development. That is, the plant is at its unjointed or immature development stage.

The extraction is preferably carried out by squeezing, crushing and/or grinding processes, not by a cutting process.

Preferably the extract from the cereal plants comprises substantially only the water soluble components of the juice.

The plant extract may be used in the concentration in which it is derived from the plants. Alternatively, if desired, the extract may be concentrated and some or substantially all the liquid content of the plant extract may be removed. For example, the extracted plant matter may be dried, such as by spray drying to yield a powder for mixing with the carrier.

The spray drying is preferably carried out at a temperature of about 50°C and preferably below 60°C.

Other possible stabilisation processes for the juice include partial concentration of the derived juice to provide a concentrated liquid. freeze drying of the derived juice. and blending the derived juice with a preserving agent forming an ingredient of the carrier.

Preferably the stabilisation or mixing with the carrier or both is carried out within a short time and preferably within two hours after extraction.

In an alternative possibility the extract may be produced by firstly drying plant matter after which the dried material is comminuted to yield a powder which includes ingredients originally in the juice.

The carrier for the extract may be any suitable material such as a liquid (e.g. water or other solvent). cream. lotion. oil. gel or powder. For example the carrier may comprise a liquid in which the extract is dissolved or vanishing cream which is intended to be absorbed through the skin when applied so as to thereby carry the plant extract into sub-cutaneous tissue. A water based or aqueous carrier capable of carrying water soluble ingredients to sub-surface tissues is preferred. Benzyl alcohol is a suitable carrier component for transdermal take up of the active ingredients.

The carrier for the extract may comprise the same carrier as used for the primary chemical treatment. For example. antibiotics can be administered to an animal in a lotion or cream to be applied topically or externally. In such a case the substance of the kind described can be mixed with the primary treatment substance in the same carrier for simultaneous administration. Likewise. antibiotics or other primary treatment substances can be administered intravenously and. subject to obvious precautions concerning composition and concentrations. the substance of the kind described can be mixed with the

intravenous solution for simultaneous administration. Of course, it will be appreciated that the primary treatment substance and secondary treatment substance can be administered separately in their respective carriers. e.g. the primary substance intravenously and the secondary substance transdermally, or the primary substance by ingestion and the secondary substance by sublingual administration and transdermal absorbtion through oral mucous tissues.

Preferably the carrier includes an anti-microbial agent so as to kill or at least inhibit growth, reproduction or activity of contaminating organisms that may be present in the plant extract or may be introduced during production of the substance. Preferably the anti-microbial agent is an anti-bacterial agent. In addition or alternatively the agent may have anti-fungal and anti-yeast properties. The anti-microbial agent may be added to the substance during production or may be present in the carrier if the carrier for example is a standard commercially available product. The anti-microbial agent is preferably active to inhibit any activity of organisms and thereby is operative to inhibit spoilage of the substance, e.g. spoilage of the product when being stored by the user or by a commercial outlet.

If the anti-microbial is not provided, it is preferred that the extract is substantially sterile when mixed with the carrier. The plants from which the extract is derived may be grown hydroponically for example under sterile conditions to prevent the introduction of micro-organisms at that stage. The subsequent harvesting and processing may also be carried out under sterile conditions.

The ratio of the extract to the carrier may be anywhere within a large range of possible ratios. For example the ratio of base carrier to plant extract (and other additives if

provided) may be anywhere between 1 to 5 and 200 to 1 (by weight). A range of 1 to 30% by weight of extract is preferred.

Preferably the substance has a generally neutral pH in the range 6.0 to 8.0. For example, the pH may be in the range 6.5 to 7.5.

Use of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is preferably by external application so that the substance is taken up by the body by absorption through the skin or mucous tissues. A particularly preferred method of transdermal uptake is by applying the substance to the mouth for uptake through mucous tissues of the mouth. For example, the substance may be administered sublingually, e.g. in the form of drops of the substance taken orally and held in the mouth under the tongue for a short time. It is found that this method of administration is effective for uptake of the substance into the body. A suitable formulation is available commercially under the registered trade mark Oralmat, manufactured by Schumacher Pharmaceuticals Pty Ltd of Melbourne, Australia. This formulation can be taken sublingually, three drops taken three times daily, to achieve the described beneficial effects.

It may also be possible (subject to obvious safeguards concerning the composition and concentration of the substance and carrier) to administer the substance subdermally by implant or injection.

The reduction of the incidence or severity of side effects associated with primary chemical treatment of the animal was unexpected and surprising and as yet the mechanism for this activity has not been determined. Indeed no obvious possible mechanism for the observed side effect reducing activity appears from the known physiological activities of the

substance according to the prior patent specification AU-81985/87 which have been seen over about the last ten years that might have suggested or predicted that activity.

The described effects of reducing incidence or severity of side effects have been observed in use of the secondary substance as a simultaneous adjunct treatment of patients being treated for chronic fatigue syndrome with a primary treatment substance in the nature of an antibiotic.

The accelerated recovery with reduced or shortened incidence or severity of side effects has been observed in race horses undergoing primary chemical treatment for injury or pathological conditions.

These observed examples of reduction of the incidence or severity of side effects in chronic fatigue syndrome patients and in race horses indicate applicability of the present invention as an adjunct treatment for an animal, including a human, being treated for a pathological or injured or abnormal condition involving administration of a primary chemical treatment, particularly antibiotics. However, the observed advantageous effects in side effects reduction indicates that the present invention is also applicable as a precautionary or preventative treatment, e.g. before, during or after a traumatic event or before, during or after an observed or expected immuno compromised or vulnerable condition, e.g. pre or post operative periods. The adjunct treatment of an animal according to the present invention promises a substantial reduction or amelioration of side effects in such circumstances.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal. the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

2. The use as claimed in claim 1 wherein the juice is derived from rye grass (Secale Cereale).

3. The use as claimed in claim 1 or 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

4. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.

5. The use as claimed in any one of the preceding claims wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

6. The use as claimed in claim 5 wherein the primary treatment substance comprises an antiobiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the

animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A substance as claimed in claim 7 wherein the juice is derived from rye grass (Secale Cereale).

9. A substance as claimed in claim 7 or 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

10. A substance as claimed in any one of claims 7 to 9 wherein the liquid extract comprises substantially only the water soluble components of the juice.

11. A substance as claimed in any one of claims 7 to 10 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

12. A substance as claimed in claim 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of treating an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating

animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

14. A method as claimed in claim 13 wherein the juice is derived from rye grass (Secale Cereale).

15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20. A method as claimed any one of claims 13 to 19 wherein the primary substance comprises an antibiotic substance.

21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the juice is derived from rye grass (secale cereale).

25. An adjunct secondary treatment substance as claimed in claim 23 or 24 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the liquid extract comprises substantially only the water soluble components of the juice.

27. An adjunct secondary treatment substance as claimed in any one of claims 23 to 26 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

28. An adjunct secondary treatment substance as claimed in claim 27 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

29. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be

taken up by the animal being treated. the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. A method as claimed in claim 29 wherein the juice is derived from rye grass (Secale Cereale).

31. A method as claimed in claim 29 or 30 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

32. A method as claimed in any one of claims 29 to 31 wherein the liquid extract comprises substantially only the water soluble components of the juice.

33. A method as claimed in any one of claims 29 to 32 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

34. A method as claimed in any one of claims 29 to 33 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

35. A method as claimed in claim 34 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

36. A method as claimed any one of claims 29 to 35 wherein the primary substance comprises an antibiotic substance.

37. A method as claimed in claim 36 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

38. A method as claimed in claim 36 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159

**A. CLASSIFICATION OF SUBJECT MATTER**

Int Cl[7]: A61K 35/78, A61P1/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61K 35/78, A61P 1/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: Cereal, Rye, Ryegrass, Secale Cereals, Barley, Wheat, Triticum, T Durum, T Compactum, Triticale, Corn, Rice, Oats, Maize, Sorghum, Millet, Extract, Side effects, Indigestion, Gas Production, Eructation, Constipation, Diarrhoea, Rash, Headache, Nausea, Dizziness

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No.. |
|---|---|---|
| X | WO 91/11191 A (RUDOV DAVID) 8 August 1991<br>Whole document | 7,9-12<br>23,25-28 |
| X | US 3787591 A (YOSHIHIDE HAGIWARA) 22 January 1974<br>Whole document | 7,9-12,23,<br>25-28 |
| X | AU 81985/87 A (RUDOV DAVID) 9 June 1988<br>Whole document | 1,3-7,9-13,<br>15-23,25-29,31-38 |

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
2 November 2000

Date of mailing of the international search report
14 NOV 2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | Patent Abstract of Japan, JP 2000044459 (TEKUNOOBURU: KK) 15 February 2000 | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | EP 0620007 A (SOKEN CO.LTD) 19 October 1994 Whole document | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | CN 1098851 (TAIPINGYANG SCIENCE AND TECH 1 (CN) 22 February 1995 | 1,3-7,9-13, 15-23,25-29,31-38 |
| X | CN 1106227 (ZHENXING ROODSTUFF FACTORY SHE (CN) 9 August 1995 | 1,3-7,9-13,15-23,25-29,31-38 |
| X | WO 95/06459 A (HELSINKI UNIVERSITY LICENSING LTD) 9 March 1995 Whole document | 1,3-7,9-13, 15-23,25-29,31-38 |
| A | HIDVEGI ET AL, CANCER BIOTHERAPY AND RADIO PHARMACEUTICALS (1999) 14, No.4, 277-289 | 1-38 |
| X | BHATTACHARYA ET AL, SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY (1998) 33, 159-163 | 1,3-7,9-13,15-23, 25,29,31-38 |

# INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 00/01159

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| WO | 91/11191 | AU | 72175/91 | | | | |
| US | 3787591 | NONE | | | | | |
| AU | 81985/87 | CA | 1298558 | DK | 6335/87 | EP | 279984 |
| | | HK | 1184/94 | NZ | 222758 | SG | 1087/94 |
| | | US | 4943433 | WO | 88/04176 | | |
| JP | 00044459 | NONE | | | | | |
| EP | 620007 | CA | 2115707 | JP | 6298658 | US | 5728384 |
| CN | 1098851 | NONE | | | | | |
| CN | 1106227 | NONE | | | | | |
| WO | 95/06459 | AU | 75384/94 | EP | 717613 | FI | 933833 |

END OF ANNEX

PATENT COOPERATION TREATY

PCT



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

| Applicant's or agent's file reference Schu6 | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
|---|---|---|
| International Application No. **PCT/AU00/01159** | International Filing Date *(day/month/year)* 25 September 2000 | Priority Date *(day/month/year)* 24 September 1999 |

International Patent Classification (IPC) or national classification and IPC

**Int. Cl.** [7] A61K 35/78, A61P 1/00

Applicant

RUDOV, David

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

[X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 7 sheet(s).

3. This report contains indications relating to the following items:

| | | |
|---|---|---|
| I | [X] | Basis of the report |
| II | [ ] | Priority |
| III | [ ] | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | [ ] | Lack of unity of invention |
| V | [X] | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | [ ] | Certain documents cited |
| VII | [ ] | Certain defects in the international application |
| VIII | [ ] | Certain observations on the international application |

| Date of submission of the demand | Date of completion of the report |
|---|---|
| 23 April 2001 | 1 November 2001 — 13 NOV 2001 |
| Name and mailing address of the IPEA/AU | Authorized Officer |
| AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | **SHUBHRA CHANDRA**<br>Telephone No. (02) 6283 2264 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

national application No.
**PCT/AU00/01159**

**I. Basis of the report**

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1-10,** as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages , filed with the demand,
  pages **11-17,** received on **31August 2001** with the letter of **31August 2001**
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] Contained in the international application in written form.
- [ ] Filed together with the international application in computer readable form.
- [ ] Furnished subsequently to this Authority in written form.
- [ ] Furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|---|---|---|
| Novelty (N) | Claims **1-37** | **YES** |
| | Claims | **NO** |
| Inventive step (IS) | Claims **1-37** | **YES** |
| | Claims | **NO** |
| Industrial applicability (IA) | Claims **1-37** | **YES** |
| | Claims | **NO** |

2. Citations and explanations (Rule 70.7)

D1 AU 81985/87

D2 Patent abstract of Japan, JP 2000044459

D3 EP 0620007

D4 CN 1098851

D5 CN 1106227

D6 WO 95/06459

D7 BHATTACHARYA ET AL SCANDINAVIAN JOURNAL OF GASTROENTROLOGY (1998) 33, 159-163.

D8 WO 91/11191

D9 US 3787591

None of the above mentioned citations disclose or suggest the invention as defined in the amended claims. Therefore, Claims 1-37 are novel and inventive.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

2. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, wherein the product includes a primary substance used for the primary chemical treatment and a secondary substance, the primary substance being mixed in the same pharmaceutically acceptable carrier or excipient as the secondary substance the secondary substance comprising a pharmaceutically acceptable extract from a juice derived from cereal plants.

3. The use as claimed in claim 2 wherein the juice is derived from rye grass (Secale Cereale).

4. The use as claimed in any one of the preceding claims wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

5. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.

6. The use as claimed in any one of the preceding claims wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A product for the treatment of animals including humans including a primary substance used for a primary chemical treatment of the animal and a secondary substance for the adjunct treatment of the animal to reduce the incidence or severity of side effects associated with the primary chemical treatment, the primary substance being mixed in the same carrier or excipient as the secondary substance, the second substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants, whereby both the primary substance and the secondary substance are administered to the subject simultaneously.

9. A substance as claimed in claim 8 wherein the juice is derived from rye grass (Secale Cereale).

10. A substance as claimed in claim 7, 8 or 9 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

11. A substance as claimed in any one of claims 7 to 10 wherein the liquid extract comprises substantially only the water soluble components of the juice.

12. A substance as claimed in any one of claims 7 to 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of precautionary or preventative treatment of an animal, including a human, of side effects associated with a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

14. A method as claimed in claim 13 wherein the juice is derived from rye grass (Secale Cereale).

15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20. A method as claimed any one of claims 13 to 19 wherein the primary substance comprises an antibiotic substance.

21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for application to

and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

25. An adjunct secondary treatment substance as claimed in claim 23 or claim 24 wherein the liquid extract comprises substantially only the water soluble components of the juice.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

27. An adjunct secondary treatment substance as claimed in claim 26 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

28. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a

secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

29. A method as claimed in claim 28 wherein the juice is derived from rye grass (Secale Cereale).

30. A method as claimed in claim 28 or 29 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

31. A method as claimed in any one of claims 28 to 30 wherein the liquid extract comprises substantially only the water soluble components of the juice.

32. A method as claimed in any one of claims 28 to 31 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

33. A method as claimed in any one of claims 28 to 32 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

34. A method as claimed in claim 33 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

35. A method as claimed any one of claims 28 to 34 wherein the primary substance comprises an antibiotic substance.

36. A method as claimed in claim 35 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

37. A method as claimed in claim 35 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal. the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

2. The use as claimed in claim 1 wherein the juice is derived from rye grass (Secale Cereale).

3. The use as claimed in claim 1 or 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

4. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.

5. The use as claimed in any one of the preceding claims wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

6. The use as claimed in claim 5 wherein the primary treatment substance comprises an antiobiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the

animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A substance as claimed in claim 7 wherein the juice is derived from rye grass (Secale Cereale).

9. A substance as claimed in claim 7 or 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

10. A substance as claimed in any one of claims 7 to 9 wherein the liquid extract comprises substantially only the water soluble components of the juice.

11. A substance as claimed in any one of claims 7 to 10 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

12. A substance as claimed in claim 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of treating an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating

animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

14. A method as claimed in claim 13 wherein the juice is derived from rye grass (Secale Cereale).

15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20. A method as claimed any one of claims 13 to 19 wherein the primary substance comprises an antibiotic substance.

21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the juice is derived from rye grass (secale cereale).

25. An adjunct secondary treatment substance as claimed in claim 23 or 24 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the liquid extract comprises substantially only the water soluble components of the juice.

27. An adjunct secondary treatment substance as claimed in any one of claims 23 to 26 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

28. An adjunct secondary treatment substance as claimed in claim 27 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

29. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance. a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be

taken up by the animal being treated. the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. A method as claimed in claim 29 wherein the juice is derived from rye grass (Secale Cereale).

31. A method as claimed in claim 29 or 30 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

32. A method as claimed in any one of claims 29 to 31 wherein the liquid extract comprises substantially only the water soluble components of the juice.

33. A method as claimed in any one of claims 29 to 32 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

34. A method as claimed in any one of claims 29 to 33 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

35. A method as claimed in claim 34 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

36. A method as claimed any one of claims 29 to 35 wherein the primary substance comprises an antibiotic substance.

37. A method as claimed in claim 36 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

38. A method as claimed in claim 36 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.